

IN THE CLAIMS:

Please amend the claims as follows; cancel claim 21 without prejudice or disclaimer of subject matter; and add new claim 25. The following is a complete listing of claims and replaces all prior versions and listings of claims in the present application.

1. (Currently Amended) An intravaginal drug delivery device for administration into a vaginal environment, the device comprising at least one reservoir, the at least one reservoir containing at least one pharmacologically active agent or a prodrug thereof, dispersed in a hydrophobic elastomeric polymer; and a hydrophobic elastomeric sheath discontinuously surrounding the at least one reservoir so as to define one or more holes or openings, each hole or opening extending through the sheath to the at least one reservoir, so that, in use, at least part of the at least one reservoir is directly exposed to the vaginal environment, wherein each hole or opening is substantially cylindrical with a diameter in the range of about 0.5 to 6.5 mm and the total surface area of the reservoir exposed to the vaginal environment through the one or more holes or openings, when in use, is in a range of 1 to 750mm², wherein the sheath is impermeable to the at least one pharmacologically active agent or the prodrug thereof, ~~and~~ wherein the at least one pharmacologically active agent or the prodrug thereof is released from the hydrophobic elastomeric polymer of the at least one reservoir through the surface area of the reservoir that is exposed to the vaginal environment, and wherein the drug has a molecular weight greater than 400 Daltons and is delivered at a pharmaceutically acceptable rate.

2. (Cancelled)

3. (Currently Amended) ~~At~~ The intravaginal drug delivery device according to Claim 1, in which the at least one hole or opening extends partially into the at least one reservoir.

4.-5. (Cancelled)

6. (Currently Amended) ~~At~~ The intravaginal drug delivery device according to Claim 1, in which the at least one hole or opening extends through the sheath substantially normal to the reservoir surface.

7. (Currently Amended) ~~At~~ The intravaginal drug delivery device according to Claim 1, in which the device is a ring that is substantially circular in transverse cross-section, and the at least one hole or opening extends substantially radially through the sheath at the inner circumference of the ring or at outer circumference of the ring.

8. (Currently Amended) ~~At~~ The intravaginal drug delivery device according to Claim 7, in which there are one to thirty of said holes or openings along the inner or outer circumference of the intravaginal drug delivery device.

9. (Currently Amended) ~~At~~ The intravaginal drug delivery device according to Claim 1, in which the device is a substantially cylindrical rod device, and said at least one hole or opening is provided at each terminal end of the rod.

10. (Currently Amended) ~~And~~ The intravaginal drug delivery device according to Claim 9, in which the rod device defines a right circular cylinder and each base of the rod is partly or fully exposed, to define said holes.

11. (Currently Amended) ~~And~~ The intravaginal drug delivery device according to Claim 9, in which further holes or openings are provided extending substantially radially through the sheath.

12. (Currently Amended) ~~And~~ The intravaginal drug delivery device according to Claim 11, in which there are one to thirty of said further holes or openings, along the circumference of the rod.

13. (Currently Amended) ~~And~~ The intravaginal drug delivery device according to Claim 1, in which the device is a partial or complete toroid shape.

14. (Currently Amended) ~~And~~ The intravaginal drug delivery device according to Claim 1, in which the reservoir additionally comprises at least one pore-forming excipient.

15. (Currently Amended) ~~And~~ The intravaginal drug delivery device according to Claim 14, in which the pore-forming excipient comprises a water-soluble or water-swellaable polysaccharide, a monosaccharide or a disaccharide, water-soluble salt, a protein, a nonionic surface active agent, a bile salt, an organic solvent, or a fatty acid ester.

16. (Currently Amended) ~~And~~ The intravaginal drug delivery device according to Claim 1, in which the sheath comprises at least one additional pharmacologically active agent.

17.-18. (Cancelled)

19. (Currently Amended) ~~An~~ The intravaginal drug delivery device according to Claim 1, ~~which is capable of~~ wherein a daily release rate of the drug is in the order of milligrams per day.

20. (Currently Amended) ~~An~~ The intravaginal drug delivery device according to Claim 1, ~~which is capable of delivering~~ wherein the drug is relatively hydrophilic ~~and/or relatively large molecular size/volume/weight drugs at a pharmaceutically suitable rate.~~

21. (Cancelled)

22. (Currently Amended) A method of delivering ~~relatively hydrophilic and/or relatively large molecular size/volume/weight drugs~~ a drug having a molecular weight of greater than 400 Daltons at a pharmaceutically suitable rate from an intravaginal drug delivery device, the method comprising administering the intravaginal drug delivery device into a vaginal environment, the device comprising at least one reservoir, the at least one reservoir containing at least one pharmacologically active agent or a prodrug thereof, dispersed in a hydrophobic elastomeric polymer; and a hydrophobic elastomeric sheath discontinuously surrounding the at least one reservoir so as to define one or more holes or openings, each hole or opening extending through the sheath to the at least one reservoir, so that, in use, at least part of the at least one reservoir is directly exposed to the vaginal environment,

wherein each hole or opening is substantially cylindrical with a diameter in the range of about 0.5 to 6.5 mm and the total surface area of the reservoir exposed to the vaginal environment through the one or more holes or openings, when in use, is in a range of 1 to 750mm², and

wherein the sheath is impermeable to the at least one pharmacologically active agent or the prodrug thereof₁ and

wherein the at least one pharmacologically active agent or the prodrug thereof is released from the hydrophobic elastomeric polymer of the at least one reservoir through the surface area of the reservoir that is exposed to the vaginal environment.

23. (Currently Amended) The method of claim 22, in which the drug ~~has a molecular weight greater than 400 Daltons~~ is relatively hydrophilic.

24. (Currently Amended) The method of claim 22, in which the intravaginal drug delivery device ~~is capable of~~ has a daily release rate of the drug in the order of milligrams per day.

25. (New) The method of claim 22, further comprising:
dissolving individual molecules of the dispersed at least one pharmacologically active agent or a prodrug thereof into the reservoir,
diffusing the dissolved at least one pharmacologically active agent or a prodrug thereof to the surface of the reservoir, and
releasing the diffused at least one pharmacologically active agent or a prodrug thereof through the one or more holes or openings in the sheath directly into the vaginal environment.